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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,368	07/29/2003	Luiz Belardinelli	02-479-C	6263

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EXAMINER

CRANE, LAWRENCE E

ART UNIT PAPER NUMBER

1623

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/629,368	<b>Applicant(s)</b> BELARDINELLI, LUIZ	
	<b>Examiner</b> L. E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/16 & 8/27/04; 3/4/05; 2/17 & 4/11/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5 documents</u> . | 6) <input type="checkbox"/> Other: _____  |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

The instant abstract is too brief because it fails to identify the particular active ingredient(s) required to carry out the instant claimed process.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as of the date of this Office action. Five Information Disclosure Statements (5 IDSs) filed January 16, 2004, August 27, 2004, March 4, 2005, February 17, 2006 and April 11, 2006 have been received with all cited references and made of record.

Claims **1-30** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-15, 17-24 and 30** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

The definitions of active ingredients in claims **1-15, 17-24 and 30** are directed to a vast number of chemical compounds which have not been described in the instant disclosure in a manner permitting the ordinary practitioner to have the guidance necessary to make a very large proportion of the compounds encompassed. Examiner finds only **CVT-3033 and CVT-3146** as compounds described prior to the "Examples" section and both of these compounds have been tested to determine how to apply this compound in the method of imaging disclosed and claimed herein. Therefore, the scope of the claims listed above wherein the functional term "A<sub>2A</sub> receptor agonist" is found in independent or dependent claims is deemed to be excessive because the noted term is clearly functional and therefore encompasses all compounds with the noted activity without identifying the particular compounds encompassed.

Claims **1-15, 17-24 and 30** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: the claims are directed to administration of any compound which has an agonist effect in binding at an A<sub>2A</sub> receptor in a human host in need of examination of cardiac blood circulation using a radionuclide as a contrast agent wherein the agonist is specified for some claims as the compounds "CVT-3164" and "CVT-3033." The possible co-administration of CVT-3164 and CVT-3033 is also claimed.

B. The nature of the invention: the invention is directed to pharmaceutical compositions containing an "A<sub>2A</sub> receptor agonist" sometimes specified as CVT-3164 or CVT-3033 or a combination thereof, to a method of selective cardiac vasodilation, and to a method of cardiac imaging in the presence of a radionuclide.

C. The state of the prior art: the prior art includes numerous references which anticipate the instant claimed subject matter.

D. The level of one of ordinary skill: one of ordinary skill should be expected to have a high level of expertise in light of the numerous references which anticipate the instant disclosures wherein the compounds CVT-3164 and CVT-3033, but would be expected to have a much lower level of expertise in the vast area of subject matter encompassed by the term "A<sub>2A</sub> receptor agonist." There is no data directed to the administration of "combinations" of CVT-3164 and CVT-3033.

E. The level of predictability in the art: the level of predictability is very high when the compounds CVT-3164 and CVT-3033 are the agonists, but very low when the other possible agonists are the compounds to be administered as a pharmaceutical composition.

F and G. The amount of direction provided by the inventor and the existence of working examples: the inventor has clearly described how to administer CVT-3164, but has not described how to administer any other agonist, including CVT-3033 or combinations of CVT-3164 and CVT-3033, in the instant method of imaging and related method of inducing selective myocardial vasodilation.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive for the claims which are directed to "A<sub>2A</sub> receptor agonists" in view of the absence of adequate guidance required by one of ordinary skill to determine how to practice the instant claimed invention with compounds other than CVT-3164 and CVT-3033 or combinations of CVT-3164 and CVT-3033.

Claims **5 and 25** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **5** the term "iv bolus" appears to include a technical abbreviation for -- intravenous --. Applicant is respectfully requested to define such abbreviations at their first occurrence in a independent claim or a dependent claim following an independent claim: e.g. -- 3'-deoxy-3'-azidothymidine (AZT) --. See also claim **25** wherein the same abbreviation first appears following an independent claim.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-11** of copending Application No. **11/253,322**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of imaging and the alleged active ingredient (CVT-3164) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **21-61** of copending Application No. **10/766,403**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 14-27, 29-30, 34 and 36-37 of copending Application No. 11/070,768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

Claims 1-30 are rejected under 35 U.S.C. §102(e) as being anticipated by **Zablocki et al.** '567 (PTO-1449 ref. A13).

Applicant is referred to claims 1, 8, 10 and 11-13 wherein the compound, also known as CVT-3164, is disclosed as part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.

See also **CV Therapeutics** '779 (PTO-1449 ref. B2) which is the PCT equivalent to the '567 reference and also anticipates the instant noted claims for the same reasons.

Claims **1-15, 17-24 and 30** are rejected under 35 U.S.C. §102(b) as being anticipated by **Verani '317** (PTO-1449 ref. **A11**).

The instant methods are anticipated by the noted reference at column 2, lines 54-67 and the continuation into column 3, column 3, lines 43-67, the EXAMPLES at columns 5-10, and by claims **1-3 and 15-23** wherein the instant methods are disclosed.

Claims **1-30** are rejected under 35 U.S.C. §102(a) and/or (b) as being anticipated by **Gao et al.** (PTO-1449 ref. **C2**).

Applicant is referred to the reference at its abstract wherein both CVT-3033 and CVT-3164 are disclosed as having the desirable properties of inducing short term coronary vasodilation during myocardial imaging in the presence of radionuclides. The copy of the reference indicates a publication date of July, 2001, which without more complete date information is deemed to be sufficient to render the instant claimed subject matter anticipated.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims **1-30** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Zablocki et al. '567** (PTO-1449 ref. **AB1**).

The instant claims are directed to methods of selective cardiac vasodilation for the purpose of enhancing the imaging of cardiac circulation by administration of an A<sub>2A</sub> receptor agonist including the compounds CVT-3164 and CVT-3033.

**Zablocki et al. '567** (PTO-1449 ref. **AB1**) discloses in claims **1, 8, 10 and 11-13** and in associated textual explanations that the compound, also known as CVT-3164, is part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.



**Zablocki et al. '567** does not expressly disclose all of the specific details of the administration of pharmaceutical compositions containing CVT-3164 found in the instant claims.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to conduct routine experimentation to determine the optimal conditions of administration of a CVT-3164-containing compositions to produce the best possible radionuclide-based cardiac circulatory imaging.

Therefore, the instant claimed method of inducing selective myocardial vasodilation for the purpose of enhancing the imaging of cardiac circulation would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

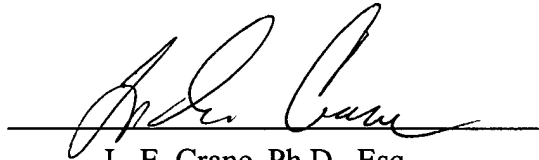
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec  
**05/23/2006**

A handwritten signature in black ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.

Patent Examiner

Technology Center 1600